

REMARKS

The above-captioned application has been carefully reviewed in light of the non-final Office Action to which this Amendment is responsive. Claims 1-3, 6, and 8-10 have been amended in an effort to further clarify and particularly point out that which is regarded as the invention and new Claims 11 and 12 have been added. To that end, it is believed no new matter has been added.

Claims 1-10 are pending. Each of the pending claims have been rejected in light of certain prior art and also based on certain paragraphs of Section 112. Applicant respectfully requests reconsideration based on the amended and new claims as well as the following discussion.

Turning to the prior art rejections, Claims 1-10 have been rejected as being anticipated by Hughes (U.S. Patent No. 3,449,081) under 35 USC §102(b). Applicant respectfully herein traverses this rejection. In order to anticipate under the Statute, each and every claimed limitation must be found in the single cited reference.

In relevant part, Hughes describes a test kit that includes a bottle for containing and dispensing a liquid reagent. The bottle 12, as shown in Fig. 4 of Hughes, includes a reservoir portion for containing a liquid reagent and a cap end 14 having an opening for dispensing the liquid reagent. The dispensing/cap end of the bottle includes several contiguous cylindrical volume elements, as viewed in a direction looking toward the opening of the dispensing end. The only opening of the bottle, however, is the opening that is provided at the dispensing/cap end.

The Examiner has stated that "Hughes discloses a clear, tapered, plastic cap (tip) that includes upper and lower openings and stepped portions therein".

The present invention relates to a metering tip having two openings. As taught, for example on page 2, paragraph [0027] of the present disclosure, a metering tip includes "a lower tip opening" and an "upper tip opening". One opening of the metering tip serves both to aspirate and dispense a fluid and the remaining opening may serve, among other purposes, to reversibly couple the metering tip to a proboscis. The bottle that is taught by Hughes includes only a single opening used only to dispense liquid reagent contained therein. There is no teaching in this reference of "upper and lower openings" for the bottle described therein.

Moreover, the dispensing/cap end of the bottle is not taught to be a separable element of the bottle. A careful reading of Hughes and examination of Fig. 4 indicates clearly that the bottle is a single molded article – the dispensing/cap end being integral therewith, that is, continuous and inseparable from the bottle.

Each of independent Claims 1 and 6 have been amended to more clearly point out that the metering tip includes a pair of openings; that is, an upper tip opening and a lower tip opening. In addition, these claims have been further amended to positively note that the lower tip opening is used to both aspirate and dispense fluid. As noted, Hughes includes a single opening that is used only to dispense fluid. Because Hughes fails to include these features there can be no anticipation of Claims 1 and 6 under the Statute. Dependent Claims 2-5, 7 and 8 are also believed allowable for the same reasons. Reconsideration is respectfully requested.

As to independent Claim 9, this claim has been amended to more clearly define method steps for performing the latching function of a fluid meniscus of an aspirated fluid. The claim has been amended to specify that fluid is aspirated into the interior of the tip and that a meniscus of the aspirated fluid is then latched by a sharp diametrical edge. Support is found in the specification – see for example, paragraph [0024] and Figs. 4-10. Therefore, no new matter has been added. Hughes does not aspirate reagent using the bottle 12 – only dispensing is performed. No suggestion or teaching regarding the varying diameter of Hughes bottle is discussed and clearly none with regard to a latching step. As a result, it is believed Claim 9 as amended can not be anticipated by Hughes. Claim 10 is believed to be allowable for the same reasons. Reconsideration is therefore respectfully requested.

It is further worthwhile to point out that there is also no apparent teaching in this reference to a “clear” bottle, as opined by the Examiner. Indeed, there instead appears to be no reason for the bottle of Hughes to be clear. The liquid reagent contained in the bottle is dispensed into a cuvette having been pre-marked to receive a specific and predetermined volume of the liquid reagent. See col. 3, lines 1 and 2. As taught in Hughes, the amount of reagent in the bottle is sufficient to accommodate all of the tests in a kit. Therefore, there would be no apparent need to know the amount of liquid reagent remaining in the bottle at any time. As noted in col. 4, lines 20-33, the large bottle 12 containing the reagent 13, is at

some point inverted and squeezed to dispense enough fluid to reach the second mark 39 in the cuvette 17, see Fig. 3. Hughes does not teach or suggest any reason for the bottle to be "clear". As such, it is therefore believed that this reference does indeed fail to include or suggest a window for reading or other purposes, as positively recited in Claims 3-8 and 10.

Claims 3-8 have been further rejected under 35 USC §103(a) based on the combination of Hughes and Treptow et al. (U.S. Patent No. 5,844,686). Applicant respectfully traverses this rejection. In order to maintain a successful "prima facie" obviousness rejection under the Statute, each and every essential claim limitation must be found in or suggested by the prior art. There must be suggestion found in the prior art as a whole to combine references together to create the claimed invention. To that end, each cited reference must be read in its entirety and not in a piecemeal fashion using impermissible hindsight (i.e., advance knowledge) of the invention.

Claims 1 and 6 have previously been discussed with regard to the primary cited reference of Hughes.

This rejection has been made by the Examiner in the event that Hughes does not include "windows". As discussed above, Applicant believes that the primary reference fails to include windows or any deducible reason to include a read window in the bottle 12.

In relevant part, Treptow et al. describes a system for pipetting and evaluating samples. The system includes a pipette tip comprising "two plane-parallel windows 8, 9 on opposite sides of its wall" (col. 4, lines 57-58). Treptow et al. neither teaches nor suggests, however, "a pipette tip having a plurality of adjacent internal stepped areas".

The Examiner asserts that it would have been obvious to one of ordinary skill in the art "to modify the cap/tip of Hughes et al [sic] to incorporate the optical windows as taught by Treptow et al. in order to provide a cap of test kit to allow for 'on-the-spot' analytics of the samples".

Hughes does not teach the bottle or its "cap/tip" as a reaction vessel or as a cuvette for optical detection of a reaction product. The liquid reagent contained within the bottle, as taught by Hughes, is dispensed into a separate and distinct container – which container serves as both the reaction vessel and the cuvette for optical detection of reaction product. Moreover, if the bottle of Hughes were "clear" as stated by the Examiner, there would be no evident need and hence no motivation to incorporate a "window" as taught by Treptow et al. for optical detection of its contents. On the other hand, if the bottle is not "clear", there is no need for detecting its contents, as previously discussed above – the change in the amount of

reagent contained is entirely predetermined and fixed by usage. There is no teaching or suggestion to be found in either reference or from the art in general that would have lead one of ordinary skill in the field to modify the bottle of Hughes by incorporating a "window" as taught by Treptow et al.

Furthermore, if the bottle of Hughes were modified to include a window as in Treptow et al., it still would fail to lead to the claimed metering tips due to the structural distinction and disparity of the bottle taught by Hughes and a metering tip of the present invention and as claimed according to Claims 1 and 6, as amended.

Therefore, Applicant believes that a "*prima facie*" case of obviousness cannot be made based on the references of record when considered either individually or in combination since neither teach or suggest the claimed metering tips or their use. Reconsideration is respectfully requested.

Claims 1, 2, 5, 6, 8 and 9 have been rejected under 35 USC §112, second paragraph, for failing to particularly point out and distinctly claim the present invention.

First, the Examiner asserts that the term "sharp" as recited in Claims 1, 6 and 9 is relative. To that end, each of Claims 1, 6 and 9 have been amended to more clearly define the term with regard to its structural features.

The amendment is supported by the figures and discussion and does not constitute new matter. In general, an edge is formed when two surfaces meet. The surfaces can meet at any angle. Considering Fig. 3 of the present disclosure, it is clear that an interior surface of a cylindrical volume element meets the surface of a stepped area at a right angle. An edge formed from orthogonal or substantially orthogonal surfaces is "sharp" in this unambiguous sense.

The Examiner has also stated that the "axial portion" as recited in Claim 2 and the term "axial section" in Claim 6 are unclear. The Examiner has further stated that it is unclear which "diameter" is being referenced in these claims.

Claims 2, 6 and 9 have been amended in order to further clarify the nature of the limitation imposed on a volume element of a metering tip. The terms "axial portion" and "axial section" have been deleted. The metering tips of Claims 2 and 6 have now been limited to those having an interior that comprises a cylindrical region having a substantially constant internal diameter. This amendment is supported by the figures and also by the disclosure, see, for example, paragraph [0031]. Therefore, no new matter has been added.

The Examiner has also stated that the "tip opening" referenced in Claims 1 and 5 and the "distal opening" of Claims 6 and 8 are ambiguous.

Claims 1 and 6 have now been amended more clearly to recite the tip openings of the metering tip wherein the lower tip opening is used to aspirate and dispense a fluid. This amendment finds support, for example, in Fig. 12 and also in paragraphs [0030]-[0033].

The Examiner has also stated that the method of Claims 9 and 10 "is not clearly defined for simply providing a structure". It is further argued that the "specification, while being enabling for achieving the method by aspirating the fluid and latching an air bubble within the tip as explained in detail within paragraphs [0028 and 0029], does not reasonably provide enablement for simply providing the structure".

As noted above, Claim 9 has now been amended to include the steps of aspirating a fluid into the lower tip opening of the metering tip and moving a meniscus of the fluid past a sharp edge in order to latch the meniscus and thereby reduce oscillation of the fluid in the metering tip. The foregoing amendment finds support throughout the specification, see paragraph [0028].

In summary, it is believed the above captioned application is now in an allowable condition and an expedited Notice of Allowability is earnestly solicited.

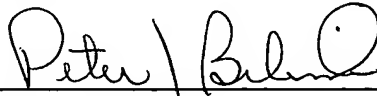
If the Examiner wishes to expedite disposition of the above-captioned patent application, he is invited to contact Applicant's representative at the telephone number below.

The Director is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0289.

Respectfully submitted,

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